

was conducted. **RESULTS:** Overall, 20,488 cases were included in the analysis. After the adjustment for age, sex, body-mass-index and duration of education there is a statistically significant association between consumption of tobacco and HRQoL in all subscores as well as both composite scores of the SF-12. The regression coefficients for current smoking (all non-smokers as reference group) are relatively small with -0.68 (role physical) to -1.35 (general health) points for physical domains and between -0.58 (vitality) and -1.47 (mental health) points for mental domains. These differences increase considerable for elderly persons (age of 50 or older, $N = 9830$) with -1.274 (role physical) to -1.87 (general health) points for physical and -0.953 (vitality) to -1.682 (social functioning) for mental scales. Equally, there is a strong statistical association between the current amount of smoking (per 10 cigarettes per day) and HRQoL (-0.342 to -0.858 for physical and -0.47 to -1.07 for mental domains, $N = 5560$). **CONCLUSIONS:** In particular, the findings are limited by the inconclusive causality direction for smoking and mental health. However, these results confirm the existing evidence concerning the negative association between smoking status or smoking intensity and HRQoL in a general population.

PRS39

VALIDATION OF THE SPANISH VERSION OF THE "COPD AND ASTHMA SLEEP IMPACT SCALE (CASIS)" QUESTIONNAIRE

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OBJECTIVES: To validate the Spanish version of the specific questionnaire "COPD and asthma sleep impact scale (CASIS)" which measures the impact of sleep quality in patients with COPD on their HRQoL. **METHODS:** Observational, prospective, multicenter study in patients with moderate/severe COPD. Data were collected at inclusion and at day 15, including the Spanish version of CASIS (7 items, range: 7 best–35 worst) and the "gold standard" Saint George Respiratory Questionnaire (SGRQ). Additionally, socio-demographics, clinical data and one item about self-perceived change in health status between visits were recorded. Feasibility, validity, reliability (internal consistency, test-retest) and responsiveness to change of the CASIS Spanish version were evaluated. **RESULTS:** A total of 142 patients were included, 87.1% males, mean age (SD) was 67.4(8.2) years, 52.7% with primary studies, 75% former smokers, FEV₁ (%) = 48.5%, (SD = 13.3), 51.3% stage II, 37.6% stage III and 11.1% stage IV. Mean (SD) score in CASIS was 18.5(6.5). CASIS questionnaire showed low levels of absent information: the mean number of items not responded per patient was <0.1, and no item accumulated more than 1 missing response. Ceiling effects of CASIS (proportion of patients accumulated in the maximum possible score) were null, and floor effects (proportion of patients accumulated in the minimum possible score) were 7.5%. CASIS showed low internal consistency (Cronbach's alpha <0.50) but an excellent test-retest reliability among patients who reported subjective stability in their health status (inter-class correlation coefficient = 0.88). Correlations between CASIS and SGRQ global scores were high (0.71) and correlations between CASIS and SGRQ dimensions were moderate to high (0.62 to 0.69). Significant differences ($p < 0.01$) in LCOPD were observed in exacerbated patients who reported an improvement, with a high effect size (0.90). **CONCLUSIONS:** According to preliminary results, Spanish version of CASIS showed satisfactory psychometric properties in terms of feasibility, validity, reliability and responsiveness to change.

PRS40

IMPACT OF COUGH AND/OR SPUTUM SYMPTOMS ON HEALTH-RELATED QUALITY OF LIFE IN COPD PATIENTS: AN OBSERVATIONAL, CROSS-SECTIONAL STUDY IN EUROPE AND THE USA

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OBJECTIVES: It is hypothesised that cough and/or sputum symptoms have a negative impact on health-related quality of life (HRQoL) in chronic obstructive pulmonary disease (COPD). This study assessed the impact of these symptoms on HRQoL in 396 COPD patients. **METHODS:** Data were drawn from the Respiratory Adelphi Disease Specific Programme conducted in France, Germany, Italy, Spain, the UK and the USA in 2008. Information collected included physicians' perceptions of symptom severity. Patients were invited to fill out a questionnaire that included EQ-5D. Variables analysed were age, gender, body mass index, breathlessness, smoking status, co-morbidities (heart-related and anxiety/depression), compliance, most recent forced expiratory volume in 1 second (FEV₁, if available) and country of origin. Due to a highly skewed EQ-5D distribution, three regression methods were applied (Tobit, OLS and GLM) to assess the impact of these variables on HRQoL. Final models derived included statistically significant variables only ($p < 0.05$). **RESULTS:** Using all three methods, cough and/or sputum were significant predictors of worse HRQoL compared with COPD patients not experiencing these symptoms. FEV₁ was only a significant predictor of better HRQoL in the Tobit approach. In this model, patients with moderate or severe cough and/or sputum symptoms presented with worse HRQoL compared with the wider COPD population (-0.09 , 95% CI -0.14 , -0.04). FEV₁ values 30–50% predicted are associated with higher EQ-5D (0.006, $p < 0.05$). However, no further significant impact was present at FEV₁ >50% predicted. In the Tobit model, patients not viewed as fully compliant with the current drug regimen were also associated with worse EQ-5D (-0.09 , $p < 0.05$). Similar statistically significant variables were observed using the GLM and OLS models. **CONCLUSIONS:** Presence and severity of cough and/or sputum in COPD has a marked association with worse HRQoL, independent of FEV₁ measurements. These results indicate unmet therapeutic needs in this population.

VALIDATION OF THE SPANISH VERSION OF THE "LIVING WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (LCOPD)" QUESTIONNAIRE

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OBJECTIVES: To validate the Spanish version of the quality of life (QoL) specific questionnaire for patients with COPD "Living with Chronic Obstructive Pulmonary Disease" (LCOPD). **METHODS:** Observational, prospective, multicenter study in a sample of patients with moderate/severe COPD. Data were collected at inclusion and at day 15, including the Spanish version of LCOPD (22 items, range: 22 worst—44 best) and the "gold standard" Saint George Respiratory Questionnaire (SGRQ). Additionally, socio-demographics, clinical data and one item about self-perceived change in health status between visits were recorded. Feasibility, validity, reliability (internal consistency, test-retest) and responsiveness to change of the LCOPD Spanish version were evaluated. **RESULTS:** A total of 142 patients were included, 87.1% males, mean age (SD) was 67.4 (8.2) years, 52.7% with primary studies, 75% former smokers, FEV₁ (%) = 48.5%, (SD = 13.3), 51.3% stage II, 37.6% stage III and 11.1% stage IV. Mean (SD) score in LCOPD was 33.0 (6.7). LCOPD questionnaire showed low levels of absent information: the mean number of items not responded per patient was <0.1, and no item accumulated more than 1 missing response. Floor and ceiling effects of LCOPD (proportion of patients accumulated in the minimum and maximum possible scores, respectively), were low (6%). LCOPD showed satisfactory levels of reliability: high internal consistency (Cronbach's alpha = 0.94) and excellent test-retest reliability among patients who reported subjective stability in their health status (inter-class correlation coefficient = 0.92, $p < 0.001$). Correlations between LCOPD and SGRQ global scores were very high (0.85), and correlations between LCOPD and SGRQ dimensions were moderate to high (0.60 to 0.87). Significant differences ($p < 0.05$) in LCOPD were observed in exacerbated patients who reported an improvement, with a small to moderate effect size (0.31). **CONCLUSIONS:** According to preliminary results, Spanish version of LCOPD showed satisfactory psychometric properties in terms of feasibility, validity, reliability and responsiveness to change.

PRS42

VALIDATION OF THE SPANISH VERSION OF THE "COPD AND ASTHMA FATIGUE SCALE (CAFS)" QUESTIONNAIRE

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OBJECTIVES: To validate the Spanish version of the health specific questionnaire to evaluate the impact of fatigue on patients with COPD "COPD and asthma fatigue scale (CAFS)". **METHODS:** Observational, prospective, multicenter study in a sample of patients with moderate/severe COPD. Data were collected at inclusion and at day 15, including the Spanish version of CAFS (12 items, range: 12 best–60 worst) and the "gold standard" Saint George Respiratory Questionnaire (SGRQ). Additionally, socio-demographics, clinical data and one item about self-perceived change in health status between visits were recorded. Feasibility, validity, reliability (internal consistency, test-retest) and responsiveness to change of the CAFS Spanish version were evaluated. **RESULTS:** A total of 142 patients were included, 87.1% males, mean age (SD) was 67.4 (8.2) years, 52.7% with primary studies, 75% former smokers, FEV₁ (%) = 48.5%, (SD = 13.3), 51.3% stage II, 37.6% stage III and 11.1% stage IV. Mean (SD) score in CAFS was 36.7 (12.1). CAFS questionnaire showed low levels of absent information: the mean number of items not responded per patient was <0.1, and no item accumulated more than 1 missing response. Floor and ceiling effects of CAFS (proportion of patients accumulated in the minimum and maximum possible scores, respectively), were low (<2%). CAFS showed satisfactory levels of reliability: high internal consistency (Cronbach's alpha = 0.88) and excellent test-retest reliability among patients who reported subjective stability in their health status (inter-class correlation coefficient = 0.85). Correlations between CAFS and SGRQ global scores were high (0.79), such as the correlations between CAFS and SGRQ dimensions (0.63 to 0.74). Significant differences ($p < 0.01$) in LCOPD were observed in exacerbated patients who reported an improvement, with a high effect size (0.90). **CONCLUSIONS:** According to preliminary results, Spanish version of CAFS showed satisfactory psychometric properties in terms of feasibility, validity, reliability and responsiveness to change.

PRS43

RELIABILITY AND VALIDITY OF THE SMOKER COMPLAINT SCALE

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OBJECTIVES: The aim of this study was to determine the reliability and validity of the Smoker Complaint Scale for the Turkish population. **METHODS:** The research was conducted in the university students. For pretest study forty students were chosen as a sampling group. After the assessment of the results, the Smoker Complaint Scale was applied to 250 students who quit smoking. Of the students are 54% female and 46% male. The original instrument was translated into Turkish and then translated back into English by two independent translators. For psychometric measures, a small sample was used to check the initial comprehension and facilitability. Cronbach's Alfa was used to assess reliability and factor analysis to assess dimensionality. The EuroQol-5D was used for concurrent validity. **RESULTS:** The internal consistency coefficient (Cronbach's alpha) of SCS was 0.912. Factor analysis of the scale revealed that it was composed of 5 factors with Eigenvalues >1.0, accounting for 77.9% of the total variance. All the items of the Turkish SCS had a factor load ranging from 0.587